

Due Diligence & Gap Analysis

With our broad experience in the medical device industry worldwide, Qserve is pleased to offer Due Diligence & GAP Analysis services. Due Diligence & GAP Analysis are essential tools for reducing the risk to potential investors and prospective buyers of medical device companies.

Such audits normally emphasize financial performance or other key business aspects of a target company, and might neglect the regulatory and quality management systems risks. Medical device companies operate in heavily regulated environments. The ability of a medical device company to meet requirements and fulfill regulations is, more often than not, the determining factor in a company's viability and profitability. Qserve can assist you with Due Diligence or GAP Analysis processes whether you are considering:

- Acquisition
- Substantial Investment
- Joint Venture
- Other commercial relationship,(e.g. exclusive distribution rights), or
- Any commercial transaction which might commit your company to significant regulatory exposure

Our certified, highly-competent Lead Auditors are your guarantee for the most effective and cost efficient Due Diligence & GAP Analysis process. We have many years of senior management experience in the medical device industry and the skill-set required to conduct these assessments. As needed, we can offer on-site services or off-site reviews in those instances where the company is able to provide all the documentation necessary to conduct a thorough and reliable appraisal.

We can be of assistance with the assessment of both research compliance and regulatory and quality management system compliance, whatever the jurisdiction. Qserve will highlight those areas requiring the most scrutiny. For example, if you are looking to acquire a company with novel technology, then a detailed examination of pre-clinical and clinical data is warranted. We will also consider distribution activities. What is the status of the target company and its devices in the world market? What is the likelihood of obtaining regulatory approval in key foreign markets? Are there any compliance issues which might hinder a proposed distribution agreement?

Through a comprehensive assessment, Qserve's expert consultants will establish the target company's compliance history, its current relationships with the regulatory authorities, and its ability to deal effectively with any compliance problems that may arise. Qserve will identify any outstanding non-conformity issues, the consequences, including financial, of remedying such problems, and your risk exposure, both current and future. A key advantage of working with Qserve is that, unlike many companies that provide due diligence services, we can also assist you with any remedial actions that may be necessary. The need to correct regulatory problems may lead to a downward adjustment in purchase price. Timely identification of these problems will help save you time and money!

If you are contemplating any kind of investment in a medical device company and you require more information or would like a free consultation and price quotation, please contact us.